IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ASHLEY PUGH, *et al.,*	:	
Plaintiffs,	:	
	:	
v.	:	Civil No. 5:20-cv-00630-JMG
	:	
COMMUNITY HEALTH SYSTEMS, INC., *et al.,*	:	
Defendants.	:	

MEMORANDUM

GALLAGHER, J. **May 10, 2023**

Plaintiffs Ashley Pugh and Daniel Pugh, individually and as parents and guardians of Minor-Plaintiff Sean Pugh bring medical malpractice and negligence claims against Northampton Hospital Company, LLC d/b/a/ Easton Hospital ("Easton Hospital"); Northampton Clinic Company, LLC d/b/a Easton Area Obstetrics & Gynecology Associates ("EAOG"); and Dr. Douha Sabouni, M.D. *See* Am. Compl., ECF No. 80. Plaintiffs allege Defendants committed medical negligence during Mrs. Pugh's delivery of her son, Sean Pugh. As a result of Defendants' negligence, Plaintiffs allege Sean suffers various injuries, including autism. Before the Court is two *Daubert* motions to preclude Plaintiffs' expert opinion concerning the general and specific causes of Sean's autism, and relatedly, one summary judgment opinion on causation. In addition to filing her own *Daubert* motion, Defendant Douha Sabouni, M.D., moves to join and/or adopt and incorporate by reference Defendant Easton Hospital and Defendant EAOG's *Daubert* and summary judgment motion and related supplemental brief in support of precluding Plaintiffs' autism causation opinion and granting summary judgment. For the following reasons, Defendant Dr. Sabouni's two motions to join and/or adopt and incorporate by reference will be granted; Dr. Sabouni's *Daubert* motion to preclude Plaintiffs' expert opinion concerning the general and

specific causes of Sean's autism will be granted; and Defendants Easton Hospital and EAOG's *Daubert* and summary judgment motion will be granted in part concerning the *Daubert* motion to preclude Plantiffs' autism causation opinion. The Court defers from granting Defendants Easton Hospital and EAOG's summary judgment motion on causation pending supplemental briefing from the Parties.

1. FACTUAL BACKGROUND

Plaintiffs Ashley Pugh and Daniel Pugh, individually and as parents and guardians of Sean Pugh bring medical malpractice and negligence claims against Defendants Easton Hospital, EAOG, and Dr. Sabouni. *See* Am. Compl., ECF No. 80. Plaintiffs allege Defendants acted negligently when providing services to Mrs. Pugh during her delivery of Sean.

In late 2013, Mrs. Pugh was twenty-six years old and pregnant with her first child. ECF No 80 ¶19. Mrs. Pugh attended EAOG for routine check-ups, including an ultrasound. *Id.* ¶¶19-20. On January 7, 2014, while Mrs. Pugh was thirty-two weeks and five days into gestation, the ultrasound indicated Mrs. Pugh's baby was normal with a fetal heart rate (FHR) of 141 beats per minute (BPM). *Id.* ¶¶21-22.

On January 22, 2014, Mrs. Pugh went to Easton Hospital after experiencing a partial rupture of membranes and intermittent leaking. *Id.* ¶23. Mrs. Pugh was admitted to Easton Hospital and began labor. *Id.* ¶24. Throughout the day, Mrs. Pugh was tended to while in labor. *Id.* ¶¶28-36. Defendant Dr. Sabouni began caring for Mrs. Pugh. *Id.* ¶36. At 7:00 p.m., Plaintiffs allege, Dr. Sabouni, "stated that she would let Mrs. Pugh 'continue to push until 9:00 p.m.' and 'then do a c-section.'" *Id.* ¶39. Defendants noted Mrs. Pugh became increasingly tired. *Id.* ¶¶41-47. At 9:00 p.m., Mrs. Pugh alleges she asked for the c-section Dr. Sabouni referenced earlier and Dr. Sabouni responded, "You're close, you can get him out." *Id.* ¶ 48.

Plaintiffs allege an Obstetrics (OB) Provider Progress Note at 9:30 p.m. showed the following message: "Impression: non reassuring fetal heart rate." *Id.* ¶53. The same note provides: "patient was pushing from 7 till 8 o'clock then felt tired. . . . Stop pushing from 8 till 8:30 then restart pushing . . . . [FHR] cat 2 variable decelerations and at 9:39 sec[ond] to maternal exhaustion [c-section] was called while preparing for [c-section] patient was feeling urge and was pushing." *Id.* ¶54. Dr. Sabouni called for a cesarean delivery (c-section) and directed Mrs. Pugh to continue pushing until the operating room ("OR") team assembled. *Id.* ¶55. The detectable FHR increased to 175, with baseline changes of "tachycardia".[1] By 10:30 p.m., no c-section team had assembled to deliver Mrs. Pugh's baby. *See id.* ¶¶61-62. The FHR had decreased to a baseline rate of 165. *Id.* ¶62. Mrs. Pugh continued to push. *Id.* ¶62. At 10:42 p.m., the baby's FHR had decreased to a baseline rate of 145. *Id.* ¶63. Baby Sean was delivered at 10:43 p.m. at thirty-five weeks. *Id.* ¶64. Baby Sean was born at a weight of five pounds and ten ounces; he was in "profound stress; his body was limp and without a heart rate; he had no first gasp or respiration; and he maintained Apgar scores of "0" during his first one to ten minutes of life.[2] Sean's heart rate went undetected

[1] *Id.* ¶57. The Court understands "tachycardia" to mean "relatively rapid heart action." *See Fetal Tachycardia*, CINCINNATI CHILDREN'S HOSPITAL, https://www.cincinnatichildrens.org/health/f/fetal-tachycardia#:~:text=Fetal%20tachycardia%20is%20a%20type,above%20180%20BPM%20at%20times (last updated January 2023).

[2] *Id.* ¶¶65-68. An Apgar score "is a test given to newborns soon after birth." *What is the Apgar Score?*, NEMOURS CHILDREN'S HEALTH, https://kidshealth.org/en/parents/apgar0.html (last reviewed February 2018). "This test checks a baby's heart rate, muscle tone, and other signs to see if extra medical care or emergency care is needed." *Id.* "Babies usually get the test twice: [one] minute after birth, and again [five] minutes after they're born." *Id.* "If there are concerns, a baby may get the test again." *Id.* The Apgar scores five things on a scale of zero [0] to two [2], with 2 [two] being the best score. *Id.* The five factors Apgar scores are: appearance (skin color), pulse (heart rate), grimace response (reflexes), activity (muscle tone), and respiration (breathing rate and effort). *Id.* "Doctors, midwives, or nurses [then] add up these five factors" to produce an Apgar score between ten and zero. *Id.* Apgar scores of zero would indicate the baby presents: bluish-gray or pale all over, no pulse, no response to stimulation, no movement, no breathing. *Id.* "A

until he was twenty minutes of age. *Id.* ¶70. A neurologist then explained to Mr. and Mrs. Pugh "Sean had suffered fetal acidemia and hypoxemia" and would be transferred to Lehigh Valley Hospital.[3]

Plaintiffs further allege "[a]n MRI five days after Sean's birth showed brain damage, and liver [and] kidney damage." ECF No. 80 ¶76. And a later "MRI showed 'hypoxic ischemic injury.'" *Id.* ¶78. Hypoxic ischemic injury such as hypoxic ischemic encephalopathy (HIE) "is a type of brain dysfunction (brain injury) that occurs when the brain experiences a decrease in oxygen or blood flow" and "can occur before birth, during labor and delivery or after birth."[4] Sean spent many weeks in various hospitals. ECF No. 80 ¶77, 80. On March 12, 2014, Sean was discharged "with a diagnosis of 'severe perinatal asphyxia [or the failure to establish breathing at birth] with multisystem involvement' and 'global developmental delay.'"[5]

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slightly low score (especially at [one] minute) is common," but there may be concerns if a baby's score does not improve at the five-minute test. *Id.*

[3] *Id.* ¶72. Hypoxia is "[l]ow levels of oxygen in the tissues." Patricia A. Heale, *Fetal Monitoring and Umbilical Cord Gases: What's the Secret?*, TEXAS CHILDREN'S HOSPITAL, https://www.texaschildrens.org/sites/default/files/uploads/documents/health_professionals/kaleidoscope/Day%201%20Fetal%20Monitoring%20and%20Umbilical%20Cord%20Gases.pdf. And acidemia is a "state of low blood pH." *Id.*

[4] *Hypoxic Ischemic Encephalopathy: Causes and Symptoms*, MASS GENERAL FOR CHILDREN (Mar. 1, 2022), https://www.massgeneral.org/children/hypoxic-ischemic-encephalopathy#:~:text=Hypoxic%20ischemic%20encephalopathy%20(HIE)%20is,and%20delivery%20or%20after%20birth.

[5] *Id.* ¶780; *see also Perinatal Asphyxia*, WORLD HEALTH ORG., https://www.who.int/teams/maternal-newborn-child-adolescent-health-and-ageing/newborn-health/perinatal-asphyxia#:~:text=Birth%20asphyxia%2C%20defined%20as%20the,causes%20of%20early%20neonatal%20mortality. (last visited May 8, 2023).

Plaintiffs allege Defendants acted negligently and/or carelessly while providing services to Mrs. Pugh during her delivery, which led to Sean Pugh's resulting injuries, including, inter alia: "fetal acidemia; hypoxemia; permanent developmental delay and cognitive impairment; speech and behavioral pathology; autism; physical growth impairment; cardiac murmur; dilated aortic root; physical and emotional pain and suffering; aggravation and/or exacerbation of all known and unknown pre-existing medical conditions; and a severe shock to his entire nervous system." ECF No. 80 ¶87. Notably to the present motion, Plaintiffs allege Defendants actions leading up to and during Sean's birth directly and proximately caused Sean's autism. *Id.*

Plaintiffs and Defendants' expert physicians agree Sean has been diagnosed with autism/autism spectrum disorder ("ASD").[6] And Defendants' experts acknowledge Sean's various conditions upon birth, including Sean's medical records of a HIE diagnosis, ECF No. 132-1, Enns Dep. Tr. 19: 1-15, 20:6-14, ECF No 132-2, Volkmar Dep. Tr. 32:3-10; Sean's diagnosis of "an extremely high risk for severe neuro-developmental delays," ECF No. 132-1, Enns Dep. Tr. at 22:13-22; and Sean's Apgar scores, limp appearance, and undetectable heart rate at and following birth, *id.* at 9:10-22, ECF No. 132-2, Volkmar Dep. Tr. 31:5-24. Moreover, Defendants' expert agrees Sean has been documented to have intellectual disabilities. ECF No. 132-1, Enns Dep. Tr., 27:13-15.

Defendants Easton Hospital and EAOG move to preclude Plaintiffs' causation testimony regarding the alleged cause of Sean Pugh's autism under *Daubert*. *See generally* ECF No. 125. More specifically, Easton Hospital and EAOG move to preclude Plaintiff's expert on causation,

[6] ECF No. 125 at 2-3 (conceding Sean has been diagnosed with autism). The Court notes "Autism Spectrum Disorder is a term that refers to a wide variety of autism; it is the clinical definition for autism." ECF No. 118 at 10 n. 5. So the Court uses the terms interchangeably.

Sarah Mulkey, M.D., Ph.D because Dr. Mulkey "is the only Plaintiffs' expert that opines on causation in this matter."[7] Defendant Dr. Sabouni also moves to preclude Plaintiffs' expert from offering any causation testimony regarding the alleged cause of Sean Pugh's Autism.[8] Like Easton Hospital and EAOG's *Daubert* motion, Dr. Sabouni's moves to preclude Dr. Mulkey's causation testimony as Plaintiffs' "sole causation expert."[9] Defendants do not contest Dr. Mulkey's qualifications as an expert.[10]

Dr. Mulkey has provided one expert report and two supplement reports in total. In Dr. Mulkey's September 29, 2021 expert report, Dr. Mulkey opines, inter alia, Sean experienced perinatal hypoxia-ischemia encephalopathy (HIE) at birth, which causes his "abnormal neurodevelopmental outcome of autism." ECF No. 125-9 at 10. Dr. Mulkey further provides "Sean's significant presentation of severe neonatal encephalopathy and the absence of more severe placental findings[] . . . [supports a finding] the cause of his autism outcome is the perinatal hypoxia-ischemia, although a contribution from the prolonged rupture of membranes is possible,

[7] ECF No. 125 at 12. Relatedly, Easton Hospital and EAOG also move for summary judgment for lack of causation. *See generally* ECF No. 125.

[8] ECF No. 118 at 2. And, and in the alternative, Dr. Sabouni requests a *Daubert* hearing. *Id.*

[9] ECF No. 118 at 7. Dr. Sabouni also moves to adopt and incorporate Easton Hospital and EAOG's related *Daubert* and summary judgment motion. *See generally* ECF No. 126. And relatedly, Dr. Sabouni moves to join Easton Hospital and EAOG concerning their supplemental motion to their *Daubert* motion. *See generally* ECF No. 139.

[10] Dr. Mulkey is certified by the American Board of Psychiatry and Neurology with special qualifications in child neurology. ECF No. 125-12 at 5, Mulkey Dep. Tr. 12:18-22. Dr. Mulkey currently works at Children's National Hospital in Washington, D.C. ECF No. 125-8 at 2. In her current position, Dr. Mulkey spends about half of her professional time in research, and the other half in patient care; her patient care consists of about ten to fifteen percent in post-natal follow-up of babies, fifteen percent as an attending neurologist in the NICU, and twenty percent in fetal neurology consultation. ECF No. 125-12 at 6-7, Mulkey Dep. Tr. 17:10-25, 18: 1-10.

but is not a main cause."[11] So, "[h]ad [Sean] avoided HIE, his outcome would be normal." *Id.* Dr. Mulkey provided she reviewed Sean's medical records and relevant medical literature, as well as she utilized her "education, experience, and general knowledge of the literature and [her] field of medicine" to form an opinion on the present action. *Id.* More specifically, Dr. Mulkey cites two studies in her expert report as "[a] sample of the reported increased risk for autism associated with HIE" in medical literature. *Id.* First, ". . . a nested case-control study, [finding] children with perinatal ischemic-hypoxic conditions had an increased odds of developing autism spectrum disorders."[12] And second, ". . . a population-based study of moderate to severe neonatal

[11] *Id.* The Court notes "Neonatal encephalopathy [(NE)] is clinically defined as a syndrome characterized by disturbed neurologic function occurring in the earliest days of an infant born at or beyond 35 weeks of gestation." ECF No. 118 at 7-8. At Dr. Mulkey's discovery deposition on September 21, 2022, she provided the preferred term for HIE is NE because there are different presentations of NE that may be for reasons other than HIE. *See* ECF No. 125-12, Mulkey Dep. Tr. 46:2-22. So "neonatal encephalopathy is . . . the big umbrella term under which there are babies that have neonatal encephalopathy because of hypoxia ischemia." *Id.*

[12] *Id.* (citing Darios Getahun, et al., *Association of Perinatal Risk Factors with Autism Spectrum Disorder,* 34 AMERICAN JOURNAL OF PERINATOLOGY 295 (2017). Dr. Mulkey reviewed and referenced a 2017 study titled "Association of Perinatal Risk Factors with Autism Spectrum Disorder" ("Getahun Study"). Ex. 3(a), ECF No. 132-3 at 2. The Getahun Study sought "[t]o examine the association between exposure to perinatal factors and autism spectrum disorders (ASD)." *Id.* the study "examine[d] the association between perinatal conditions and ASDs in singleton live-born children delivered in a large health maintenance organization." *Id.* at 3. "The study population was drawn from a total of 594,638 births between 1991 and 2009." *Id.* ". . . [T]he final population consisted of 401, 660 singleton, live born children." *Id.* The study then compared "[d]ifferences in maternal and child characteristics between children with and without ASDs." Id. at 4. The study found "children exposed to perinatal conditions were more likely to be diagnosed with ASD than those who were not exposed." *Id.* at 8. More specifically, researchers found "intrapartum conditions . . . [including birth asphyxia]to be significant risk factors for ASD at term birth." *Id.* And "[m]ost of the perinatal conditions-associated increase in ASDs risk is attributable to exposure to birth asphyxia with Apgar score < 7 at 5 minutes (46%) . . . ." *Id.* So "children who had birth asphyxia, Apgar score < 7 at 5 minutes and resuscitation clearly are at increased risk of ASD." *Id.* The study concluded "perinatal conditions, especially birth asphyxia and preeclampsia, are associated with increased risk of childhood ASD even after accounting for gestational age at delivery and other potential confounding factors." *Id.* at 9.

encephalopathy, [finding] children with neonatal encephalopathy were 5.9 times more likely to be diagnoses with autism than controls."[13]

Dr. Mulkey expanded on her causation opinions in two supplemental expert reports. First, Dr. Mulkey's February 4, 2022 supplemental report analyzed Sean's January 28, 2022 brain MRI. ECF No. 125-10 at 2. Dr. Mulkey then found "the brain MRI findings of white matter injury that he has . . . is consistent with the sequelae of the acute HIE he had on his brain MRI at [five] days of age." *Id.* And, Dr. Mulkey opined, Sean "has an abnormal neurodevelopmental outcome due to this injury." *Id.*

Second, Dr. Mulkey's July 30, 2022 supplemental report provided opinions in response to her review of other expert reports. *See* ECF No. 125-11 at 2. Notably, Dr. Mulkey provides "[A]utism is a multi-factorial complex neurodevelopmental disorder the cause of which can relate to a genetic condition or a multitude of other risk factors . . . ." *Id.* Dr. Mulkey then provides various citations to studies finding an association or increased risk between HIE and the

[13] ECF No. 125-9 at 10 (citing Nadia Badawi et al., *Autism following a history of newborn encephalopathy: more than a coincidence?*, 48 DEVELOPMENTAL MEDICINE & CHILD NEUROLOGY 85 (2006). The study included children with moderate or severe newborn encephalopathy (NE) shown by the following criteria: seizures, or "any two of the following lasting for longer than [twenty-four hours]: [a]bnormal consciousness, [d]ifficulty maintaining respiration . . . , [d]ifficulty feeding . . ., [a]bnormal tone and reflexes." ECF No. 132-4 at 3. The Badawi study involved "a population-based study of NE term-born infants" at least 37 weeks' gestation." *Id.* Researchers compared infants with moderate or severe NE with "564 randomly selected term controls" or infants." *Id.* The study ultimately found "an unexpected but strong association between moderate and severe newborn encephalogy (NE) and a subsequent diagnosis of autism." *Id.* More specifically, "[c]ompared with the controls, the children who had experienced NE were 5.9 times (95% confidence interval 2.0-16.9) more likely to have been diagnosed with ASD." *Id.* at 2. The researchers concluded their ". . . population-based case-control study has highlighted a strong association between moderate to severe term NE and the development of ASD." *Id.* at 5. Nevertheless, researchers conceded, "[g]iven the small number of cases involved, it is not clear from our findings what the association between NE and autism may represent." *Id.*

development of ASD.[14] Thus Dr. Mulkey finds "infants who have abnormal perinatal exposures including NE or HIE and requirement of NICU level care have an increased risk of ASD." *Id.* At 2-3. And, once again, "[h]ad [Sean Pugh] not had the condition of HIE at birth, he would not have developed ASD." *Id.* At 3. Dr. Mulkey also provided "[h]ad [a] caesarean section delivery been expediated when called at 2130 and Sean Pugh been delivered close to 2130, he more likely than not would not have had severe HIE-NE and would have had a much better and likely normal outcome." *Id.* At 5.

Before the Court is (1) Dr. Sabouni's *Daubert* motion to preclude any of Plaintiffs' experts from offering any causation testimony regarding the alleged cause of Sean Pugh's Autism, and in the alternative, request for a *Daubert* hearing, ECF No. 118; (2) Easton Hospital and EAOG's *Daubert* motion to preclude Plaintiffs' causation testimony regarding the cause of minor Plaintiff's autism and summary judgment for lack of causation, ECF No. 125; (3) Dr. Sabouni's motion for joinder and/or to adopt and incorporate Easton Hospital and EAOG's *Daubert* and summary judgment motion, ECF No. 126; and (4) Dr. Sabouni's motion for joinder and/or to adopt and incorporate Easton Hospital and EAOG's supplemental motion in support of their *Daubert* and summary judgment motion, ECF No. 139. Notably, Dr. Sabouni, Easton Hospital, and EAOG's *Daubert* motions to preclude causation testimony solely concern Plaintiffs' expert Dr. Mulkey's opinion as to the cause of Sean Pugh's autism. *See* ECF No. 125 at 12; ECF No. 118 at 2.

[14] *Id.* (providing the following citations, inter alia: Neonatal Encephalopathy and Neurologic Outcome, *Executive Summary*, 2nd Ed., 2014; Nadia Badawi et al., *Autism following a history of newborn encephalopathy: more than a coincidence?*, 48 DEVELOPMENTAL MEDICINE & CHILD NEUROLOGY 85 (2006); Chalak LF, et al., Ped Res (2018); A. Winkler-Schwartz A et al., Pediatr Neural (2014)).

On February 3, 2023, Defendant Dr. Sabouni moved to preclude Dr. Mulkey's opinion Sean Pugh's autism was caused as a result of the perinatal hypoxia-ischemia. Dr. Sabouni contends Dr. Mulkey's causation testimony should be precluded because Dr. Mulkey cannot reliably opine as to whether or not HIE actually causes autism—Dr. Mulkey only opines there is an association between HIE and autism. ECF No. 118 at 10. And, furthermore, Dr. Mulkey cannot reliably "raise[] the possibility that Ms. Pugh's prolonged rupture of membranes may ***possibly*** by the cause of Sean Pugh's autism." *Id.* at 11. So, in sum, Dr. Sabouni's *Daubert* motion concerns the reliability of Dr. Mulkey's opinions on causation. *See id.*

On February 3, 2023, Defendants Easton Hospital and EAOG also moved to exclude Plaintiffs' causation testimony regarding the alleged cause of minor Plaintiff's autism and summary judgment for lack of causation. *See generally* ECF No. 125. In sum, Defendants contend Dr. Mulkey's conclusions Sean's "autism was caused by neonatal encephalopathy/hypoxic ischemic encephalopathy (NIE/HIE)" is unreliable under the case law and state of medical literature." ECF No. 125 at 4. And thus, Defendants submit, Plaintiffs are unable to "establish that []NE/HIE[] generally causes autism or that . . . NE/HIE specifically caused [Sean Pugh's] autism." *Id.* To support their averments Dr. Mulkey's causation opinion is unreliable, Defendants contend prior case law has found expert testimony on autism causation as insufficient under the *Daubert* standard. And Defendants also submit Dr. Mulkey's causation opinion is unreliable because it is unsupported by medical literature; at best, Defendants contend "epidemiological studies show that there may be an association" between perinatal hypoxia and autism. *Id.* at 8.

Plaintiffs respond in opposition to both *Daubert* motions with similar contentions.[15] Plaintiffs argue, inter alia, Dr. Mulkey's causation testimony is sufficiently reliable because studies support perinatal hypoxia/HIE are strongly associated with and/or increase the risk of autism. ECF No. 132 at 24. Plaintiffs contend Dr. Mulkey's general causation argument is consistent with the lower burden for plaintiffs in medical malpractice actions concerning causation. *See* ECF No. 137 at 6-7. Plaintiffs also submit "relevant case law . . . firmly support an inference that HIE/NE could have caused Sean's autism." ECF No. 132 at 41 (emphasis in original). So, "Dr. Mulkey's causation opinions . . . rest on reliable methodologies and have reliable bases . . . ." *Id.* at 42.

Related to Defendants Easton Hospital and EAOG's *Daubert* motion, Defendants also move for summary judgment. ECF No. 125 at 17-19; *see also* ECF No. 126 (Dr. Sabouni requesting to join Easton Hospital and EAOG's *Daubert* and summary judgment motion). Easton Hospital and EAOG briefly contend, in the event their *Daubert* motion is granted, Plaintiffs are unable to prove the acts of Defendants caused Sean's autism. ECF No. 125 at 18-19. And Defendants also submit Plaintiffs cannot show "that some other process solely caused [Sean Pugh's] current disabilities since autism/ASD can account for all of [Sean Pugh's] disabilities." *Id.* Because, Defendants contend, "[t]here is no way to disentangle [Sean Pugh]'s intellectual functioning as the result of his autism diagnosis versus some other diagnosis or intellectual disability." *Id.* at 19. In response, Plaintiffs seem to isolate autism from Sean's other potential injuries. ECF No. 132 at 42-43. And, Plaintiffs contend, Defendants do not contest Sean's birth-related brain damage "caused him an extremely high risk for severe neuro developmental delays."

[15] *See generally* ECF Nos. 132, 137. Plaintiffs raise contentions similar in substance concerning all Defendants' motions to preclude Dr. Mulkey's causation testimony. Accordingly, the Court considers the motions in concert. Nevertheless, the Court will specify where Plaintiffs or Defendants raise a distinct argument.

Id. at 43. And, furthermore, Plaintiffs point to Defendants' own experts and contend "Defendants' causation experts agree that Sean suffers intellectual disabilities and that perinatal hypoxia/HIE can cause neuro-developmental impairs." *Id.* So, Plaintiffs aver, "[t]he record . . . [sufficiently] establishes that Defendants caused Sean's birth-related brain damage (HIE), that Sean's brain damage increased his risk of developing both autism and other neurodevelopmental disorders/delays . . . , and that Sean in fact developed both autism and other neurodevelopmental disorders." *Id.* at 45.

2. LEGAL STANDARDS

a. Causation in Medical Malpractice Claims

To prevail on their medical malpractice claims, Plaintiffs must "establish a duty owed by the physician to the patient, a breach of that duty by the physician, that the breach was the proximate cause of the harm suffered, and the damages suffered were a direct result of the harm." *Toogood v. Owen J. Rogal, D.D.S., P.C.*, 824 A.2d 1140, 1145 (Pa. 2003) (quoting *Hightower-Warren v. Silk*, 698 A.2d 52, 54 (Pa. 1997)). And "[b]ecause the negligence of a physician encompasses matters not within the ordinary knowledge and experience of laypersons a medical malpractice plaintiff must present expert testimony to establish the applicable standard of care, the deviation from that standard, causation and the extent of the injury." *Id.* (citing *Hightower-Warren*, 698 A.2d at 54).

Concerning causation, "[t]he first step is to determine whether the medical expert for the plaintiff "could testify to a reasonable degree of medical certainty that the acts or omissions complained of could cause the type of harm that the appellant suffered." *Qeisi v. Patel*, No. CIV A 02-8211, 2007 WL 527445, at *9 (E.D. Pa. Feb. 9, 2007) (quoting *Mitzelfelt v. Kamrin*, 584 A.2d 888, 894 (Pa. 1990)). And "[s]econdly, the court must 'determine whether the acts

complained of caused the actual harm suffered by the appellant.'" *Id.* (citing *Mitzelfelt*, 584 A.2d at 894). "As to the second part of the test, Pennsylvania courts apply a 'relaxed standard,' requiring only a finding that the physician's action (or omission) was a substantial factor in causing the injury. *Id.* (quoting *Mitzelfelt*. 584 A.2d at 894). Courts have labeled the dual requirements of causation as "general causation" and specific causation," respectively. *See e.g., . In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 176 F. Supp. 3d 483, 491 (E.D. Pa. 2016) (Zoloft III)) ("General causation is whether a substance [or other factor] is capable of causing a particular injury or condition in the general population, while specific causation is whether a substance [or other factor] caused a particular individual's injury."), *aff'd sub nom. In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 858 F.3d 787 (3d Cir. 2017) (quoting *Wells v. SmithKline Beecham Corp.*, 601 F.3d 375, 277–78 (5th Cir.2010) (internal quotations and citations omitted)). And "[s]equence matters: a plaintiff must establish general causation before moving to specific causation. Without the predicate proof of general causation, the tort claim fails." *Id.* In medical malpractice and negligence claims, Plaintiffs often "'must present admissible expert testimony' to prove causation because th[ese] case[s] 'involv[e] complex issues of causation not readily apparent to the finder of fact.'" *Hoefling v. U.S. Smokeless Tobacco Co.*, LLC, 576 F. Supp. 3d 262, 270 (E.D. Pa. 2021) (quoting *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 525 (W.D. Pa. 2003)).

b. Admissibility of Expert Opinions

Under the Federal Rules of Evidence, district courts must act as the gatekeepers of expert testimony. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999); FED R. EVID. 702. In *Daubert v. Merrell Dow Pharmaceuticals*, the Supreme Court held that "[f]aced with a proffer of expert scientific testimony . . . the trial judge must determine at the outset . . . whether the expert is proposing to testify to (1)

scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue." 509 U.S. at 592.

"Before testimony can reach the jury under the cloak of expertise, the Court must evaluate it for three criteria: qualification, reliability and fit." *Sec. & Exch. Comm'n v. Ambassador Advisors, LLC*, 576 F. Supp. 3d 250, 255 (E.D. Pa. 2021) (citing *UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres*, 949 F.3d 825, 832 (3d Cir. 2020)). First, a witness is ***qualified*** **t**o provide expert testimony only if the witness has "specialized expertise" in the testimony's subject matter. *Schneider ex rel. Est. of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003).

Next, a witness's testimony is ***reliable*** only if it is founded upon "good grounds." *UGI Sunbury LLC*, 949 F.3d at 834; FED. R. EVID. 702 (requiring expert testimony be "based on sufficient facts or data" and be derived from "reliable principles and methods" that have been "reliably applied . . . to the facts of the case."). The U.S. Court of Appeals for "[t]he Third Circuit has interpreted 'reliability' to mean that an expert's testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable." *Elgert v. Siemens Indus., Inc.*, No. CV 17-1985, 2019 WL 1294819, at *5 (E.D. Pa. Mar. 20, 2019) (quoting *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008) (internal citations omitted)). Accordingly, "[a]n expert's opinion must be 'based on the methods and procedures of science rather than on subjective belief or unsupported speculation.'" *Daddio v. A.I. DuPont Hosp. for Child. of Nemours Found.*, 650 F. Supp. 2d 387, 403 (E.D. Pa. 2009), *aff'd sub nom. Daddio v. Nemours Found.*, 399 F. App'x 711 (3d Cir. 2010). And "*Daubert*'s reliability analysis . . . applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, and the link between the facts and the conclusion." *Hoefling*, 576 F. Supp. 3d at 271 (quoting *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 290 (3d Cir. 2012)).

So "[a] district court is directed to the following factors to determine the reliability of proposed expert testimony: '(1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.'" *Daddio*, 650 F.Supp.2d at 403 (quoting *Schneider*, 320 F.3d at 405 (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 n. 8 (3d Cir. 1994)). "As long as an expert's scientific testimony rests upon good grounds, based on what is known, it should be tested by the adversary process." *Hoefling*, 576 F. Supp. 3d at 272.

Lastly, a witness' testimony ***fits*** a case only if it would help the trier of fact to understand the evidence or determine a fact in issue. *UGI Sunbury*, 949 F.3d at 835 (quoting FED. R. EVID. 702); *see also United States v. Ford*, 481 F.3d 215, 219 n.6 (3d Cir. 2007) ("[F]it is [primarily] a relevance concern.") (internal quotation marks omitted).

The Rules of Evidence reflect a liberal policy of admissibility, even for expert testimony. *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008); *see also Takeda Pharms. USA, Inc. v. Spireas*, No. CV 17-0452, 2019 WL 9596536, at *1 (E.D. Pa. Sept. 4, 2019). "But expert testimony **must** satisfy the requirements set out above to be admissible." *Sec. & Exch. Comm'n*, 576 F. Supp. 3d at 255 (emphasis added) (citing *UGI Sunbury LLC*, 949 F.3d at 832-33). "The burden to establish that each requirement is satisfied by a preponderance of the evidence rests with the party offering the expert testimony." *Id.* (citing *Padillas v. Stork–Gamco, Inc.*, 186 F.3d 412, 418 (3d Cir. 1999)).

3. DISCUSSION

Defendants Easton Hospital, EAOG, and Dr. Sabouni raise a series of contentions concerning the reliability Dr. Mulkey's causation opinion. The Court will first address Dr. Sabouni's various motions, ECF Nos. 126, 39, for joinder and/or to "adopt and incorporate by reference" Easton Hospital and EAOG's *Daubert* and summary judgment motion, ECF No. 125, as well as their supplement to the *Daubert* and summary judgment motion, ECF No. 139. For the reasons explained below, the Court will grant Dr. Sabouni's two motions to join and/or incorporate the motions of Easton Hospital and EAOG. The Court will then consider the two *Daubert* motions raised by Defendants to preclude Dr. Mulkey's autism causation testimony in concert. Lastly, the Court will address Defendants summary judgment opinion concerning whether Dr. Mulkey's opinion sufficiently supports Plaintiffs claims of medical malpractice and negligence.

a. Dr. Sabouni's Motions for Joinder

Dr. Sabouni moves to "adopt and incorporate in reference" Defendants Easton Hospital and EAOG's *Daubert* and summary judgment motion concerning causation "as if fully set herein at length," *see* ECF No. 126, as well as Defendants Easton Hospital and EAOG's supplemental motion in support of the *Daubert* and summary judgment concerning causation, *see* ECF No. 139. Plaintiffs did not respond in opposition to Dr. Sabouni's motions for joinder and/or "to adopt and incorporate by reference."

Federal Rule of Civil Procedure 10(c) provides "[a] statement in a pleading may be adopted by reference elsewhere in the same pleading or in any other pleading or motion." FED. R. CIV. P. 10(c). "Rule 10(c), however, provides no authority for one party to adopt by reference the arguments advanced by another party in a motion in which the first party seeks to join." *Krause v. Buffalo & Erie Cnty. Workforce Dev. Consortium, Inc.*, 425 F. Supp. 2d 352, 363 (W.D.N.Y.

2006). "Rather, where a motion to join is unopposed, the arguments proffered by the defendant initiating the motion apply equally to all co-defendants, and granting the motion to join will not prejudice the plaintiff, the motion to join is generally granted." *Id.* (citing *Gulf Coast Development Group, LLC v. Lebror*, 2003 WL 22871914, *1 n. 1 (S.D.N.Y.2003); *Sacay v. Research Foundation of City University of New York*, 44 F.Supp.2d 505, 509 (E.D.N.Y.1999)).

Here, Dr. Sabouni's motions for joinder are unopposed. The arguments made by Easton Hospital and EAOG equally apply to Dr. Sabouni as a co-defendant because Plaintiffs must prove causation as an element of their medical malpractice claims against all three Defendants. And granting Dr. Sabouni's motions to join EAOG's *Daubert* and summary judgment motion as well as their corresponding brief will result in minimal—if any—prejudice to Plaintiffs in this case. All three Defendants raise arguments with similar substance, and Plaintiff has been given ample opportunity to respond, as well as oppose any joinder. Accordingly, the Court will now consider the merits of Defendants' *Daubert* motions to preclude Dr. Mulkey's causation testimony.[16]

[16] As stated, Defendants Dr. Sabouni, Easton Hospital, and EAOG raise substantively similar arguments concerning the reliability of Dr. Mulkey's causation testimony. The issue has been comprehensively briefed, and the Court has considered numerous exhibits in addition to the Parties' briefing. "The Court has 'considerable leeway' in deciding how to test an expert's reliability and in deciding whether or not the expert's relevant testimony is reliable." *Daddio*, 650 F.Supp.2d at 403. "It thus has the same kind of latitude in deciding how to test an expert's reliability, and to decide whether or when special briefing or other proceedings are needed to investigate reliability, as it enjoys when it decides whether or not that expert's relevant testimony is reliable." *Id.* And "[t]he Court also has the discretionary authority needed both to avoid unnecessary proceedings . . . and to require appropriate proceedings." *Id.* Here, Plaintiffs and Defendants have submitted voluminous material on the subject of autism causation and the reliability of Dr. Mulkey's opinion. The Parties have not indicated there remains any specific or additional evidence to be presented at a *Daubert* hearing or in additional briefing. Accordingly, the Court declines holding a *Daubert* hearing and will consider the reliability of Dr. Mulkey's opinion based on the Parties' extensive briefing. Furthermore, the Court will consider the Defendants' arguments in concert due to their similar nature, and to avoid repetition and unnecessary confusion.

b. Defendants' *Daubert* Motions to Exclude Dr. Mulkey's General Causation Opinion

Plaintiffs offer Dr. Mulkey to provide a general causation opinion concerning an association of HIE/NE and autism/ASD, as well as a specific causation opinion based on the facts of this matter. In her expert reports, Dr. Mulkey opines "infants who have abnormal perinatal exposures including NE or HIE and requirement of NICU level care have an increased risk of ASD." ECF No. 125-10 at 2-3; *see also* ECF No. 125-9 at 10 (opining "[w]hile cerebral palsy is the developmental outcome most often seen following HIE . . . other developmental abnormalities may occur including autism"). Based on this association between the factors, Dr. Mulkey then opines that "***the cause of [Sean's] autism is the perinatal hypoxia-ischemia***, although a contribution from the prolonged rupture of membranes is possible, but not the main cause." ECF No. 125-9 at 10; *see also* ECF No. 132 at 38. She further opines if Sean "avoided HIE, his outcome would be normal." ECF No. 125-9 at 10; *see also* ECF No. 132 at 38.

In sum, Dr. Mulkey's general causation opinion provides HIE/NE "increases the risk" of autism and is "associated with" autism. ECF No. 125-10 at 2-3. Dr. Mulkey supports this conclusion with a sample of medical literature offered to show an association between HIE/NE and autism/ASD. *See generally* ECF No. 125-9 at 10. Based on this proffered relationship between the factors, Dr. Mulkey then provides a definitive statement that Sean's HIE/NE caused his autism in this case. *See id.* ("Sean had severe neonatal encephalopathy (HIE-type) at birth and has an abnormal neurodevelopmental outcome of autism. Had he avoided HIE, his outcome would be normal."). Dr. Mulkey's fails to provide reliable methodologies leading to her findings of general and specific causation. And Dr. Mulkey's specific causation opinion, based on Dr. Mulkey's general causation opinion, is too large a jump from her general causation conclusions and the data in support of her findings. Thus Dr. Mulkey will be precluded from offering (1) a

general causation opinion that HIE/NE increases the risk and/or causes autism/ASD, and (2) a specific causation opinion that Sean's HIE/NE caused his autism/ASD in this case.

i. Dr. Mulkey's Opinion Concerning General Causation

Concerning Dr. Mulkey's general causation opinion, Defendants contend the medical literature shows "[a]t best . . . there may be an association" between HIE/NE and autism. *See* ECF No. 125 at 8; *see also id.* at 11 (" . . . the most accomplished autism researchers still do not know precise methods of autism causation and never conclude associations of various environmental[*sic*] are causal."). And Defendants put forward additional studies that question an association between HIE/NE and autism and find no causal link between the factors.[17] Nevertheless, Defendants mainly contest Dr. Mulkey's general causation opinion because she "cannot establish that

[17] A few of the studies provided by Defendants include, inter alia: Chengzong Wang et al, *Prenatal, Perinatal, and Postnatal Factors Associated with Autism*," MEDICINE (May 2017), https://journals.lww.com/md-journal/Fulltext/2017/05050/Prenatal,_perinatal,_and_postnatal_factors.14.aspx (finding certain perinatal factors such as fetal distress increased the risk of autism, while other factors such as premature membrane rupture and a five-minute Agpar score under seven were not associated with an increased risk of autism, but "[t]hese factors could interact or contribute in combination with other cofactors to play a role in the development of autism" and "[f]urther studies are needed to . . . investigate the singe or combination factors for autism.") (ECF No 125-3); Hannah Gardener, Donna Spiegelman, and Stephen Buka, *Perinatal and NeoNatal Risk Factors for Autism: A Comprehensive Meta-Analysis*, 128(2) PEDIATRICS 344 (2011), https://publications.aap.org/pediatrics/article-abstract/128/2/344/30617/Perinatal-and-Neonatal-Risk-Factors-for-Autism-A?redirectedFrom=fulltext (concluding "[t]here is insufficient evidence to implicate any 1 perinatal or neonatal factor in autism etiology, although there is some evidence to suggest that exposure to a broad class of conditions reflecting general compromises to perinatal and neonatal health may increase the risk") (ECF No. 125-4);
Janet M. Rennie, Cornelia F. Hagmann, and Nicole J. Robertson's, *Outcome After Intrapartum Hypoxic Ischaemia at Term*, 12 SEMINARS IN FETAL & NEONATAL MEDICINE 398 (2007) (finding "no evidence that, in isolation, either attention deficit hyperactivity disorder or autism is caused by hypoxic ischaemia"); and Imen Hadjkacem et al, *Prenatal, Perinatal and Postnatal Factors Associated with Autism Spectrum Disorder*, 92(6) JORNAL DE PEDIATRIA 595 (2016) (in a study of fifty children, finding fetal distress, including oxygen deprivation, as a risk factor for autism but but also finding "[i]n the present study, no individual factor in the prenatal period was consistently significant as a risk factor for ASD").

(NE/HIE) generally ***causes*** autism" based on literature showing, at best, only an ***association*** between the factors. ECF No. 125 at 4 (emphasis added). But Defendants' averments miss the mark—it is possible Dr. Mulkey **could** provide a causal opinion from the existing medical literature, but she does not provide a reliable methodology in forming her conclusions.

Contrary to Defendants' averments, the admissibility of an expert's causation opinion does not rely solely on whether the relative scientific community has conclusively established causation. In fact, the U.S. Court of Appeals for the Ninth Circuit has found ". . .while an expert must 'employ[ ] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field,'[18] **the standards for courtroom testimony do not necessarily parallel those of the professional publications** . . . ."[19] So "[u]nder Rule 703, *Daubert* instructs that the admissibility inquiry focuses not on conclusions, but on approaches . . . ." *Ambrosini v. Labarraque*, 101 F.3d 129, 140 (D.C. Cir. 1996). The U.S. Court of Appeals for the Third Circuit has consistently placed emphasis on an expert's methodology in determining an opinion's reliability.[20]

Accordingly, the Court first looks to the methods Dr. Mulkey utilized to come to her

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[18] *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1236 (9th Cir. 2017) (quoting *Kumho Tire Co., Ltd. v. Carmichae*l, 526 U.S. 137, 152 (1999)).

[19] *Id.* (emphasis added) (citing *Ambrosini*, 101 F.3d at 138).

[20] *See e.g., United States v. Downing*, 753 F.2d 1224, 1237 (3d Cir.1985); *accord DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3d Cir.1990). The Court notes the Third Circuit's established emphasis on methodology also renders the bulk of Plaintiffs' arguments—that "Dr. Mulkey's opinions are ***verified*** by recent case law holding that the theory that 'autism spectrum disorder can be caused by HIE' is supported by medical literature . . . ."—inappropriate under the current state of the law under *Daubert*. ECF No. 137 at 7 (emphasis in the original) (citing *Ellis v. Fortner*, 169 N.E.3d 987, 995 (Ohio Ct. of App. 2021). The Court is not bound by the decisions of other trial courts concerning different experts with their own opinions based on various methodologies. Instead, the Court will undergo a reliability analysis of the current expert in front of the Court.

general causation/association conclusions in this matter. "To meet the *Daubert* standard, the experts must demonstrate that these opinions are based on methods and procedures of science, not speculation or subjective belief, and they must possess a reasonable degree of scientific certainty regarding their causation opinions." *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F. Supp. 3d 466, 475 (E.D. Pa. 2014) (Zoloft II)). So "[t]he proponent of the evidence must show . . . that 'the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable fashion." *McMunn v. Babcock & Wilcox Power Generation Grp., Inc.*, No. 2:10CV143, 2014 WL 814878, at *6 (W.D. Pa. Feb. 27, 2014) (citing *Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998)).

One manner of exploring and establishing a casual relation is through epidemiological studies. "Epidemiology is the 'study of the distribution and determinants of health-related states and events in populations and the application of this study to control of health problems.'" *In re TMI Litig.*, 193 F.3d 613, 661 n. 81 (3d Cir. 1999), *amended*, 199 F.3d 158 (3d Cir. 2000) (citing FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 174 (1994)). "Epidemiology is concerned with the incidence of disease in populations and does not address the question of the cause of an individual's disease." *Id.* at 167. Nevertheless, federal courts have found "[e]pidemiological evidence is a manner of establishing a causal chain or relation." *Kiker v. SmithKline Beecham Corp.*, No. 2:14-CV-2164, 2016 WL 8189286, at *6 (S.D. Ohio Dec. 15, 2016) ("Epidemiologic studies are the primary generally accepted methodology for demonstrating a causal relation between the chemical compound and a set of symptoms or a disease.") (quoting *Conde v. Velsicol Chem. Corp.*, 804 F.Supp. 972, 1025-26 (S.D. Ohio 1992)); *see also Zoloft II*, 26 F. Supp. 3d at 475 ("The Court agrees that reliable expert opinions about human causation generally should be supported by positive and replicated epidemiological studies."). In fact, "some

courts express a preference for epidemiological evidence." *Kiker*, 2016 WL 8189286, at *6. Nevertheless, even with a preference for epidemiological evidence, the law under *Daubert* "discourage[es] mandates" and focuses on an expert's methodology. *Id.* at *7.

The use of epidemiological studies can be used to support emerging scientific and medical theories. "On questions . . . which stand at the frontier of current medical and epidemiological inquiry, if experts are willing to testify that such a link exists, it is for the jury to decide whether to credit such testimony." *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1534 (D.C. Cir. 1984). "Thus, a cause-effect relationship need not be clearly established by animal or epidemiological studies before a doctor can testify that, in [their] opinion, such a relationship exists." *Id.* at 1535.

"In determining if the scientific methodology is sound and well-founded, courts should consider whether others in the field use similar methodologies." *Rubanick v. Witco Chem. Corp.*, 593 A.2d 733, 748 (N.J. 1991). As stated, courts have found experts typically rely on epidemiological studies to develop medical and/or scientific theories on the causation and other relatedness of various medical outcomes. *See e.g., Zoloft II*, 26 F. Supp. 3d at 475 ("When one is interested in human causation, the most relevant evidence will come from human epidemiological studies."); *DeLuca v. Merrell Dow Pharms., Inc.*, 911 F.2d 941, 954 (3d Cir. 1990), *disapproved of on other grounds by Daubert*, 509 U.S. at 579 (1993) ("epidemiology is a well-established branch of science and medicine, and epidemiological evidence has been accepted in numerous cases"); *In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Pracs. & Prod. Litig.*, 509 F. Supp. 3d 116, 164 (D.N.J. 2020) (finding experts properly examined "the totality of the available epidemiological evidence on talc use and ovarian cancer, and drew conclusions based on sound scientific reasoning"); *Diaz v. Johnson Matthey, Inc.*, 893 F. Supp. 358, 375 (D.N.J. 1995) (considering whether an expert's opinion on specific causation is flawed where it did not rely on

a conclusive animal or epidemiological study); *Wendell*, 858 F.3d at 1233 (9th Cir. 2017) (analyzing whether the district court erred in determining the lack of animal or epidemiological studies showing a causal link between HSTCL and the combination of 6MP and anti-TNF drugs undermined the experts' methodology); *Rubanick*, 593 A.2d 733, at 741-750 (surveying the use of epidemiological studies in various cases in consideration of an expert's reliability in a toxic-tort litigation); *Ambrosini*, 966 F.2d at 1466 (considering whether the district court properly precluded an expert who reviewed epidemiological data to provide a causal opinion).

Defendants do not contest Dr. Mulkey's use of epidemiological studies in her methodology. Defendants seem to contend, nevertheless, the studies put forward by Dr. Mulkey do not conclusively establish a causal or even associative relationship between HIE/NE and autism/ASD. Defendants also aver Dr. Mulkey does not provide a complete picture of existing epidemiological studies. [21] As provided by Dr. Mulkey, "[a]utism is a multi-factorial complex neurodevelopmental disorder the cause of which can relate to a genetic condition or a multitude of other risk factors . . . ." ECF No. 125-11. Despite the complexity of her opinion's subject matter, Dr. Mulkey does not purport to perform a comprehensive survey of the literature, nor does she outline a "scientific methodology" she used to form her opinion. *See Hoefling*, LLC, 576 F. Supp. 3d at 275.

Expert opinions with "[c]ausal conclusions require examining 'the literature as a whole.'" *Hoefling*, 576 F. Supp. at 273 (quoting *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F. Supp. 3d 449, 461 (E.D. Pa. 2014) (Zoloft I) (explaining the "accepted scientific practice" is

[21] *See* ECF No. 125 at 8-11. And for further information and discussion of studies that call into question Dr. Mulkey's findings of an "increased risk for autism associated with HIE" or a causal relation between the factors, *see supra* note 17.

not for experts to "simply ignor[e] certain studies" but rather explain why they "give[] more weight" to particular studies when forming an opinion)). And "[e]xpert causation testimony 'generally should be supported by positive and replicated epidemiological studies.'" *Id.* at 274-75 (quoting *Zoloft II*, 26 F. Supp. 3d at 475). Moreover, "[a]n expert must not cherry-pick from the 'scientific landscape and present the Court with what [they] believe[] the final picture looks like.'" *Daniels-Feasel, et al., v. Forest Pharms., Inc.*, No. 17 CV 4188-LTS-JLC, 2021 WL 4037820, at *5 (S.D.N.Y. Sept. 3, 2021) (quoting *In re Rezulin Prod. Liab. Litig.*, 309 F. Supp. 2d 531, 563 (S.D.N.Y. 2004)). "Sound scientific methodology in assessing general causation requires an expert to evaluate 'all of the scientific evidence when making causation determinations.'" *Id.* (citing *Zoloft I*, 26 F. Supp. 3d at 463; *In re Abilify (Aripiprazole) Prod. Liab. Litig.*, 299 F. Supp. 3d 1291, 1311 (N.D. Fla. 2018) ("[The] 'weight of the evidence' approach to analyzing causation can be considered reliable, provided the expert considers all available evidence carefully and explains how the relative weight of the various pieces of evidence led to his conclusion."). Thus, "[w]hen an expert's causation opinion is 'equivocal or inconsistent with' epidemiological research, the expert must 'thoroughly analyze' its 'strengths and weaknesses.'" *Hoefling*, 576 F. Supp. at 273 (quoting *Zoloft II*, 26 F. Supp. 3d at 475). "[E]xclusion of proffered testimony is warranted where the expert fails to address evidence relevant to his or her conclusion." *Daniels-Feasel*, 2021 WL 4037820 at *5 (citing *In re Mirena Ius Levonorgestrel-Related Prod. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213, 242 (S.D.N.Y. 2018)).

Dr. Mulkey's methodology is much more like "cherry-pick[ing,]" *id.* at *5, than an "examin[ation] [of] 'the literature as a whole[,]" *Hoefling*, 576 F. Supp. at 273 (internal quotation omitted). Although Dr. Mulkey acknowledges causal mechanisms of autism are "complex" and researchers are currently increasing their "understanding of how [different factors] affect the

outcome of autism spectrum disorders," ECF No. 125-12 at 34-35, Mulkey Dep. Tr. 129: 17-25, 130 1-3, she does not claim to undergo an in-depth review of additional epidemiological research with "equivocal or inconsistent" findings. *Hoefling*, 576 F. Supp. at 273 (quoting *Zoloft II*, 26 F. Supp. 3d at 475). Instead, Dr. Mulkey provides a "sample" of the literature—which is consistent with Dr. Mulkey's findings of an increased risk and/or association between HIE/NE and autism/ASD—as well as her "general knowledge of the literature" to support her general causation/association opinion.[22] Moreover, in her expert reports, Dr. Mulkey did not address a single study with findings inconsistent to or questioning of her opinion, nor did she address any limitation or drawback of the few studies she offers in support of her opinion. *See generally* ECF Nos. 125-9, 125-10, 125-11. Dr. Mulkey's failure to thoroughly consider differing opinions can also be seen in her lack of independent review of the epidemiological research cited by Defendants' experts opining on the same causation issue. *See ECF* No. 125-12 at 34, Mulkey Dep. Tr. 126:15-23, 128:1-5 (explaining she had reviewed certain articles for the first time upon their reference by Defendants' experts). Dr. Mulkey's sparse overview of epidemiological studies is particularly notable considering she acknowledges the subject of her opinion is an area of great complexity with various emerging theories, and much of the medical literature on the subject discusses the

[22] ECF No. 125-9 at 10. In Dr. Mulkey's September 29, 2021 expert report, Dr. Mulkey cites two studies in her expert report as "[a] sample of the reported increased risk for autism associated with HIE" in medical literature. *Id.* The Getahun study "examine[d] the association between exposure to perinatal factors and autism spectrum disorders (ASD)." ECF No. 132-3 at 2. And the Badawi study looked to the "association between autism and several medical conditions." ECF No. 132-4 at 3. And, in her July 30, 2022 supplemental expert report, Dr. Mulkey provides various citations to studies finding an association or increased risk between HIE and development of ASD. *Id.* (providing citations for three additional studies) (internal citations omitted). But Dr. Mulkey does not perform a review of relevant studies, nor does she provide additional support beyond the few studies she identifies to support her general causation/association opinion. *See generally* ECF Nos. 125-9, 125-10, 125-11.

difficulty—or even the inability—surrounding isolating factors to consistently show they either increase the risk of or cause autism. *See e.g.*, Hannah Gardener, Donna Spiegelman, and Stephen Buka, *Perinatal and NeoNatal Risk Factors for Autism: A Comprehensive Meta-Analysis*, 128(2) PEDIATRICS 344 (2011) ("The etiology of autism is unknown, although perinatal and neonatal exposures have been the focus of epidemiologic research for over [forty] years."); *see also supra* note 17 (medical literature on the etiology of autism).

Dr. Mulkey's methodology behind her general causation/association opinion also does not amount to "scientific 'principles and methodology' that open the *Daubert* gate." *Hoefling*, 576 F. Supp. 3d at 280 (citing *Daubert*, 506 U.S. at 595). Under *Daubert*, expert opinions require "more than subjective belief or unsupported speculation." *Daubert*, 506 U.S. at 590. To determine whether an expert's opinion is sufficiently supported, district courts look to whether the expert's methodology satisfies a number of relevant factors under *Daubert*, 506 U.S. at 593-95 and *In re Paoli*, 35 F.3d at 742 n.8.

Here, Dr. Mulkey's methodology is not sufficiently precise. Dr. Mulkey explicitly opines HIE/NE increases the risk of ASD. *See* ECF No. 125-9 at 10. And Dr. Mulkey's specific causation opinion that Sean's HIE/NE caused his development of autism rests on the assumption HIE/NE can cause autism. Dr. Mulkey then contends her finding "is described in the literature and is observed in clinical practice throughout the world." *Id.* at 3. Dr. Mulkey does not describe her reasoning behind providing the few studies included in her expert reports beyond indicating they represent a "sample" of broader literature in agreement with her opinion. ECF No. 125-9 at 10. Therefore, Dr. Mulkey's expert reports and related testimony do not show her methodology "consist[s] of a testable hypothesis," has been "subject[ed] to peer review;" nor has a "known or potential rate of error." *Daddio*, 650 F.Supp.2d at 403 (internal quotations and citations omitted).

Furthermore, as stated, her method of surveying epidemiological studies to form a relational and/or causal opinion is "generally accepted . . . [and] established to be reliable[,]" *id.*, when the survey is complete and thorough concerning "equivocal or inconsistent . . . epidemiological research[,]" *Hoefling*, 576 F. Supp. 3d at 275 (quoting *Zoloft II*, 26 F. Supp. 3d at 475). Dr. Mulkey did not provide such a survey. Therefore, a number of the factors the Third Circuit has adopted to assess an expert's reliability weigh against admitting Dr. Mulkey's expert opinion on the relation between HIE/NE and autism/ASD. *In re Paoli*, 35 F.3d at 742 n. 8.

In sum, Dr. Mulkey's attempt to provide a general causation/association opinion is unreliable because she does not sufficiently outline a methodology addressing equivocal or inconsistent findings to her own. And furthermore, the Third Circuit's factors concerning reliability weigh against including her causal/relational opinion. Accordingly, her general causation finding HIE/NE "increases the risk of autism" and/or is "positively associated with autism" will be precluded as unreliable. Moreover, testimony implying HIE/NE causes autism will also be precluded for the foregoing reasoning.

ii. Defendants' Daubert Motion to Exclude Dr. Mulkey's Specific Causation Opinion

As stated, general causation concerns whether a factor is "'capable of causing a particular injury or condition in the general population,' and specific causation goes to whether it 'caused a particular individual's injury.'" *Hoefling*, 576 F. Supp. 3d at 270 (quoting Zoloft III, 176 F. Supp. 3d at 491). Thus plaintiffs "must establish general causation before moving to specific causation." *Id.* (citing *Zoloft III*, at 176 F. Supp. 3d at 491) (internal quotation omitted). Dr. Mulkey did not provide a reliable methodology supporting her opinion HIE/NE increases the risk and/or causes autism/ASD. "[E]xpert testimony is inadmissible under *Daubert* if 'any step' in the expert's

analysis makes it unreliable.'" *Id.* (quoting *Paoli*, 35 F.3d at 745). General causation is a necessary step to show specific causation.[23] Dr. Mulkey's inability to provide a reliable opinion that HIE/NE increases the risk and/or causes autism/ASD prevents her from opining that, based on the specific facts at hand, Sean's HIE/NE caused his autism/ASD outcome.

Accordingly, the Court finds—particularly in light of Dr. Mulkey's unwillingness to explicitly provide HIE/NE **can cause** autism/ASD—Dr. Mulkey's proffered opinion Sean's HIE/NE **caused** his autism/ASD outcome, ECF No. 125-9 at 10, is an inadmissible "unsupported speculation." *Id.* (citing *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 290 (3d Cir. 2012)). And, once again, the medical literature Dr. Mulkey puts forward showing a relation between HIE/NE and autism/ASD—without a proper survey of equivocal and inconsistent studies and thorough explanation of her conclusion—"is simply too great an analytical gap between the data and the opinion proffered[,]" here, concerning specific causation. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 144 (1997) (internal citations omitted). Without additional support and explanation, Dr. Mulkey's specific causation opinion based on her finding of a mere association between factors amount to an unreliable "speculative leap." *Hoefling*, 576 F. Supp. 3d at 274 (finding an expert impermissible made "'speculative leaps' in claiming that a causal link exists simply because it is biologically plausible") (quoting *Zoloft II*, 26 F. Supp. 3d at 481). "Neither *Daubert* nor Rule 702 require the Court to admit an expert's opinion that is 'connected to existing data' solely by the expert's 'ipse dixit.'" *Id.* (quoting *General Elec. Co. v. Joiner*, 522 U.S. 136, 146, (1997) (emphasis in original).

In sum, the reliability issues concerning Dr. Mulkey's general causation/association

[23] The Court notes this is true even with medical malpractice's lower standard for proving specific causation. If Dr. Mulkey cannot reliably opine HIE/NE increases the risk and/or causes autism in the general population, it logically follows she cannot reliably apply that opinion to the current set of facts and find one factor caused Sean's outcome of autism/ASD.

opinion persist concerning the specific causation testimony. Thus, precluding Dr. Mulkey's specific causation testimony on Sean's HIE/NE and autism/ASD is warranted.

Lastly, Dr. Sabouni also averred Dr. Mulkey improperly phrased her specific causation opinions so as to run afoul of Pennsylvania's requirements medical opinions must be stated "with a reasonable degree of medical certainty." *See* ECF No. 118 at 23; *see also In re Paoli*, 35 F.3d 717, 750 (3d Cir. 1994) (internal citations omitted). "Whether an expert satisfies this standard does not depend on 'magic words.'" *Hoefling*, 576 F. Supp. 3d at 285 (quoting *Commonwealth v. Spotz*, 756 A.2d 1139, 1160 (Pa. 2000)). Nevertheless, "Pennsylvania courts have long drawn a distinction between reasonable certainty and probabilistic guesswork." *See id.* (internal citations omitted). "Testimony that something was 'more likely than not' the cause of the plaintiff's injury is insufficient." *Id.* (citing *Griffin v. Univ. of Pittsburgh Med. Ctr.–Braddock Hosp.*, 950 A.2d 996, 1003 (Pa. Super. Ct. 2008)). And "an expert does not express the requisite certainty when he puts the odds in favor of his theory of causation at just above fifty-fifty." *Id.* (internal citations omitted).

Here, Dr. Mulkey opined "given Sean's significant presentation of severe neonatal encephalopathy and the absence of more severe placental findings, the cause of his autism outcome is the perinatal hypoxia-ischemia, although a contribution from the prolonged rupture of membranes is possible but is not a main cause." ECF No. 125-9 at 10. Dr. Sabouni avers Dr. Mulkey should be precluded from testifying that prolonged rupture of membranes contributed to or caused Sean Pugh's autism at trial. ECF No. 118 at 33-34. Dr. Sabouni contends Dr. Mulkey's deposition testimony shows Dr. Mulkey "does not know whether or not 'prolonged rupture of membranes' is even associated with ASD." *Id.* at 34; *see also* ECF No. 125-12 at 20, Mulkey Dep. Tr. at 70-73 (clarifying her opinion concerning the possible contribution of prolonged rupture of

membranes). But, besides brief mention in her September expert report, Dr. Mulkey does not otherwise provide a causal opinion concerning the prolonged rupture of membranes in her causal argument in her expert reports or testimony. And, the September expert report only provides prolonged rupture membranes amount to a possible contribution—"not a main cause." ECF No. 125-9 at 10. Even assuming Dr. Mulkey sufficiently shows an association or causation between prolonged rupture membranes and ASD/autism, Dr. Mulkey's deposition testimony provides her clarification that Mrs. Pugh did not present symptoms of this factor. ECF No. 125-12 at 20, Mulkey Dep. Tr. at 72:7-25, 73:2-4. Moreover, when questioned concerning this portion of her opinion, Dr. Mulkey testified that her "ultimate opinion is: had [Sean] avoided hypoxic-ischemic encephalopathy, his outcome would be normal."[24]

Therefore, the Court does not find Dr. Mulkey's testimony concerning the prolonged rupture of membranes is being offered as an opinion on causation and thus, at this time, the Court declines to preclude Dr. Mulkey's testimony concerning the prolonged rupture of membranes. The Court may revisit Defendant's motion to preclude this statement upon clarification Dr. Mulkey intends to opine on the causal effect of prolonged rupture of membranes.

c. Defendants' Summary Judgment Motion on Causation

Lastly, Defendants contend Dr. Mulkey is Plaintiffs' sole causation expert and thus, Plaintiffs would be unable prove Defendants acted negligently and caused injury in this case without her causation testimony. ECF No. 125 at 17-19. In response, Plaintiffs fail to clarify (1) whether Dr. Mulkey is indeed their sole causation expert linking Defendants' conduct to Sean's injuries in this case, and (2) if so, whether Plaintiffs can presently satisfy their burden of proving

[24] *Id.* at 20, Mulkey Dep. Tr. at 73:5-8. The Court also notes Plaintiffs' response to Defendant's averment also focuses on the Dr. Mulkey's causation argument concerning NIE/HE and autism. *See* ECF No. 137 at 37-38.

their medical malpractice claims. *See generally* ECF No. 132 at 42-45.

As stated, a plaintiff must prove the following to establish a cause of action for professional negligence and/or medical malpractice:

> (1) a duty owed by the physician to the patient (2) a breach of duty from the physician to the patient (3) that the breach of duty was the proximate cause of, or a substantial factor in, bringing about the harm suffered by the patient, and (4) damages suffered by the patient that were a direct result of that harm.

Garcia v. United States, 2022 WL 19569519, at *3 (quoting *Mitzelfelt*, 584 A.2d at 891). And a "plaintiff 'is also required to present an expert witness who will testify . . . that the acts of the physician deviated from good and acceptable medical standards, and that such deviation was the proximate cause of the harm suffered.'" *Id.* (internal citations omitted). Concerning causation, "the expert [report] must demonstrate . . . the negligence of the defendant either proximately caused, or increased the risk of its occurrence." *Id.* (quoting *Grossman v. Barke*, 868 A.2d 561, 572 (Pa. Super. Ct. 2005)).

The Court has found Dr. Mulkey's opinion on a causal relation—including general and specific causation—between HIE/NE and autism/ASD does not meet the reliability standards under *Daubert* and its progeny. But the record does not establish whether summary judgment is warranted. Dr. Mulkey's opinion concerns the causes of autism, but Plaintiffs allege Plaintiff Sean Pugh has suffered a variety of injuries beyond autism—including, inter alia, developmental delay and cognitive impairment, speech and behavioral pathology, physical and emotional pain and suffering— as a result of Defendants' alleged negligence. *See* ECF No. 80 at 10. Although Defendants boldly assert—unsupported by citation or other reference—Sean's autism "can account for each and every one of the test findings for [i]ntellectual [f]unctioning" and "[t]here is no way to disentangle [Sean's] intellectual functioning as the result of his autism diagnosis versus

some other diagnosis or intellectual disability," ECF No. 125 at 18-19, the Court is not persuaded this reasoning warrants summary judgment. Accordingly, the Court will defer ruling on Defendants' summary judgment motion, ECF No. 125 at 17-19, and request supplemental briefing from the Parties, as outlined in the Court's corresponding Order.

4. CONCLUSION

Dr. Mulkey's general and specific causation opinion and testimony are not supported by reliable methodology. Thus Dr. Mulkey will be precluded from providing testimony in the context of (1) a general causation opinion that HIE/NE increases risk and/or causes autism or ASD, and (2) a specific causation opinion that Sean's HIE/NE caused his autism/ASD in this case.

Accordingly, the Court grants Defendant Dr. Sabouni's motion to preclude any of Plaintiffs' experts from offering causation testimony regarding the alleged cause of Minor-Plaintiff, Sean Pugh's autism at trial. ECF No. 118. The Court will also grant Dr. Sabouni's joinder motions, ECF Nos. 126, 139, to join and/or adopt and incorporate (1) Defendants Easton Hospital and EAOG's *Daubert* motion to exclude Plaintiffs' causation testimony regarding the alleged cause of minor Plaintiff's autism and summary judgment for lack of causation, ECF No. 125, and (2) Defendants Easton Hospital and EAOG's supplement to their *Daubert* and summary judgment motion, ECF No. 138.

The Court also grants in part Defendants Easton Hospital and EAOG's *Daubert* motion to exclude Plaintiffs' causation testimony regarding the alleged cause of minor Plaintiff's autism and summary judgment for lack of causation. ECF No. 125. Defendants' motion will be granted concerning the *Daubert* motion to preclude Plaintiff's causation testimony. The Court defers ruling on Defendants' related summary judgment motion, *see id.*, pending supplemental briefing from the Parties, as outlined in the Court's corresponding Order.

An appropriate Order follows.

BY THE COURT:

/s/ John M. Gallagher
JOHN M. GALLAGHER
United States District Court Judge